Physician Lead Manual

DRAFT

CAUTION:

Federal law restricts this device to sale, distribution and use by or on the order of a physician.

MP9055183 Rev A

Copyright

Guarantees

Advanced Bionics Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

Registered Trademarks

Linear™, BionicNavigator™ and Precision™ are registered trademarks of Advanced Bionics Corporation. Velcro® is a registered mark of Velcro Industries, Manchester, New Hampshire. Other brands and their products are trademarks or registered trademarks of their respective holders and should be noted as such.

Table of Contents

Introduction

Manual Overview

This manual provides basic information for the implantation and use of the Advanced Bionics® Lead Model SC-2108 and Lead Extension Model SC-3108. These products are designed to be percutaneously or surgically implanted for use with the Precision™ Spinal Cord Stimulation (SCS) System to aid in the management of chronic intractable pain. Information on other system components and their operation can be found in the BionicNavigator™ Software Guide.

General surgical guidelines are presented for temporary and permanent implantation of leads and extensions.

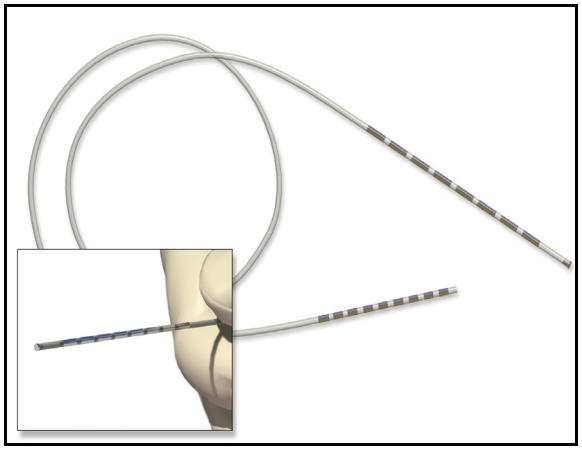
Product Description

Lead

The lead functions as a component of the Precision system by delivering electrical stimulation to the nerve structures in the dorsal aspect of the spinal cord, resulting in an inhibition of pain sensation.

Model SC-2108 has eight electrode contacts located near the distal end. Each contact is 3 mm in length and is spaced 1 mm from the adjacent contact. The lead body is made of medical grade polyurethane with a stiffer proximal end to aid insertion into the connector. To aid in intraoperative testing and positioning, a curved stylet is pre-

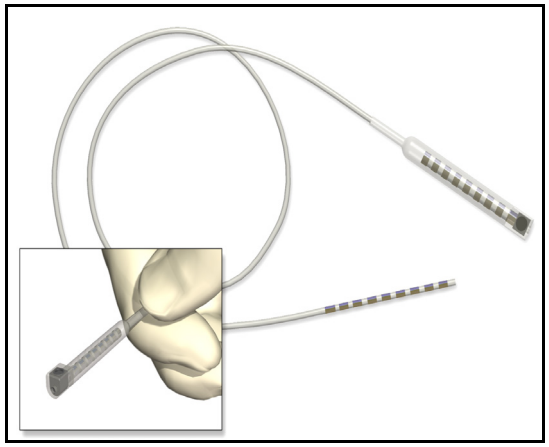
inserted into the lead. The lead can be connected to either an extension or directly to an implantable pulse generator (IPG).



Lead Extension

Lead Extension Model SC-3108 is designed to connect the Lead Model SC-2108 to the Advanced Bionics Precision implantable pulse generator for spinal cord stimulation. The extension may be added to

a lead to externalize the lead for a trial phase or to extend a lead when a permanent IPG is implanted.



Indications for Use

The Advanced Bionics Precision™ Spinal Cord Stimulator System (Precision System) is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

Precision System Clinical Summary

Determination of the safety and effectiveness of the PRECISION System was based on available published clinical studies for similar implanted spinal cord stimulation systems. The PRECISION System is similar to the SCS systems reported in published literature in intended use, target patient population, technology, device design, and output characteristics. Therefore, the clinical data from the published literature described below represents evidence supporting the safety and effectiveness of the PRECISION System for the treatment chronic intractable pain of the trunk and/or limbs, including unilateral

or bilateral pain associated with the following: failed back surgery syndrome, intractable low back and leg pain.

Efficacy Evaluation

Three (3) clinical literature studies were used to support the effectiveness of the PRECISION System (Ohnmeiss et al. 1996, Villavincencio et al. 2000, Hassenbach SJ et al. 1995). The studies included a total of 116 patients that were implanted with an SCS system. A total of approximately 3166 device months of experience was depicted from the retrospective clinical evaluation. All three studies examined the effectiveness of SCS on patients with chronic pain of the trunk and/or limbs including unilateral or bilateral pain associated with the following: failed back surgery syndrome or intractable low back and leg pain. In all studies, a totally implantable spinal cord stimulator was used in association with a percutaneous and/or surgical lead. These studies provide the same diagnostic or therapeutic intervention for the same disease/conditions and patient population as the PRECISION System.

The prospective study by Ohnmeiss et al. 1996, examined the long-term effectiveness of SCS in patients with intractable leg pain. Forty patients were implanted with SCS systems and evaluated at 6 weeks, 12 months, and 24 months follow-up. Outcome measures included the VAS, pain drawings, medication use, SIP (Sickness Impact Profile), isometric lower extremity testing, and patient questionnaires. An intent-to-treat analysis was performed. After patients had SCS for 24 months, leg pain, pain when walking, standing pain, pain's effect on overall lifestyle, and the total analog scale scores were significantly improved from baseline. In this study, 25% of the implanted patients had greater than 50% improvement in pain rating.

In addition, 3 patients from this study had their stimulators repositioned due to pain at the original location. Three patients had reoperations to adjust lead position; 1 patient required 2 reoperations, 1 patient had the device removed due to infection and later to have a new device implanted. A diabetic patient had skin problems which

required device removal; a new device was later implanted. Two patients had the device removed due to unsatisfactory pain relief.

The prospective study performed by Villavicencio et al. 2000 included 41 patients with pain of various etiologies. The majority of the patients, 24 (59%), had Failed Back Surgery Syndrome (FBSS), 7 (17%) had Complex Regional Pain Syndrome (CRPS I and II), 4 (10%) had neuropathic pain syndrome, and 6 (15%) were diagnosed as stroke or other. Patients underwent an initial trial period for SCS with temporary leads. If the trial resulted in greater than 50% reduction in the patient's pain, as measured by the VAS, the patient was implanted with a SCS system. In this study, 27/41 patients, 66%, had permanent implants. All patients were examined after 6 weeks. Pain measurements were assessed at 3-6 month intervals for the first year and annually thereafter. The median long-term follow-up was 34 months. A total of 24/27 (89%), reported greater than 50% reduction in pain. Since the majority of the patients were treated for FBSS, this article supports the use of SCS for the treatment of FBSS.

In this study, one patient required a revision because of electrode fracture. One patient required removal of the system due to local infection. One patient required replacement of the IPG due to mechanical failure. Overall, 16 of 27 (59%) patients required a total of 36 repositioning procedures.

A retrospective analysis performed by Hassenbusch SJ et al. 1995 included patients with chronic lower body pain, predominately neuropathic pain and pain either midline lower back and/or unilateral or bilateral leg pain treated over a 5 year period. The study was a comparison of SCS to spinal infusion of opiods. For patients with radicular pain involving one leg with or without unilateral buttock pain, a trial of SCS was recommended first. For patients with midline back pain and /or bilateral leg pain, a trial of long-term spinal infusion was recommended first. If the patients failed screening with either of these modalities, the other was then tested. If the treatment reduced the pain by 50%, the systems were internalized. A retrospective analysis of

patients with unilateral leg and/or buttock pain treated initially with SCS and bilateral leg or mainly low back pain treated initially with spinal infusions of opioids was then done.

In this study, 42 patients were screened; 26 (62%) patients received spinal stimulation; 16 (38%) received opioids via a spinal infusion pump. Five patients did not receive adequate pain relief with SCS; 3 (7%) of these patients underwent trial spinal infusions and had effective pain relief. There were 4 (10%) patients who underwent a trial of spinal infusion of opioid but did not receive adequate pain relief; these patients were not tested with SCS. Pain severity was rated using a verbal digital pain scale: "On a scale of 0 to 10 where 0 is no pain and 10 is the worst pain you could ever imagine, what is your pain now?" 16/26 patients (62%) had greater than 50% pain relief with SCS. In this study, 2/16 (13%) had greater than 50% pain relief with opioids. Mean follow-up was 2.1 ± 0.3 years. This analysis supports the use of SCS for intractable low back and leg pain.

In this study, 7 (17%) patients suffered complications after implantation of the device; 5 (12%) patients required repositioning of catheter type electrodes and 2 patients required revision of the stimulator generator.

Safety Evaluation

Eleven studies were identified based on the detailed inclusion/exclusion criteria to demonstrate the safety of the PRECISION System. The studies included a total of 1056 patients that were trialed with SCS systems and 880 patients that received implants. The table below depicts the number of patients, the number of events, and the percentage of occurrences of each event compared to the total number of patients. It should be noted that citations cover both IPG and RF Systems. The clinical experience reported in the literature on RF systems is relevant to determining the safety of totally implantable IPG systems.

Table 1: Summary of Risks Identified in the Retrospective Clinical Studies

Risks	# Patients With Adverse Event	Intent-to-Treat Basis N = 1056	Implanted Patient Basis N = 880
Lead Migration	175	16.6%	19.9%
Infection	39	3.7%	4.4%
Epidural Hemorrhage	0	0%	0%
Seroma	0	0%	0%
Hematoma	1	0.1%	0.1%
Paralysis	0	0%	0%
CSF Leak	5	0.5%	0.6%
Over/Under Stimulation, Ineffective Pain Control	46	4.4%	5.2%
Intermittent Stimulation	0	0%	0%
Pain Over Implant	16	1.5%	1.8%
Allergic Reaction	6	0.6%	0.7%
Skin Erosion	0	0%	0%
Lead Breakage	35	3.3%	4.0%
Hardware Malfunction	22	2.1%	2.5%
Loose Connection	0	0%	0%
Battery Failure	2	0.2%	0.2%
Other	45	4.3%	5.1%

Clinical Experience-Safety

Clinical data has been collected during a clinical study of the PRECISION™ System. As of January 15, 2004, 35 subjects were enrolled in the study at multiple sites and 26 subjects had a successful trial stimulation period and were implanted with the PRECISION™ System. The follow-up period for the 26 implanted patients ranged from two weeks to six months. The following major adverse events were reported.

Table 2: Clinical Experience Safety

Type	Number of Patients	Resolution
Lead Migration	1	Lead repositioning and subsequent replacement
Output malfunction	1	Device replaced
Infection	1	Infection treated
Pain	1	Lead explanted

Other minor adverse events reported by at least one patient included: receiver malfunction, skin irritation, unpleasant stimulation, CSF leak, infection at implant site, lead migration, and OR cable malfunction. Two of the subjects reported multiple events.

References

Burchiel, K.J., V.C. Anderson, F.D. Brown, R.G. Fessler, W.A. Friedman, S. Pelofsky, R.L. Weiner, J. Oakley,and D. Shatin. “Prospective, Multicenter Study of Spinal Cord Stimulation for Relief of Chronic Back and Extremity Pain.” Spine, 21:2786-2793, 1996.

Hassenbusch, S.J., M. Stanton-Hicks, E.C. Covington. “Spinal cord stimulation verses spinal infusion for low back and leg pain”. Acta Neurochirgica, 64:109-115, 1995.

Kemler, M.A., G.A.M. Barendse, M. Van Kleef, H.C.W. De Vet, C.P.M. Rijks, C.A. Furnee and F.A.J.M. Van den Wilderberg. “Spinal Cord Stimulation in Patients with Chronic Reflex Sympathetic Dystrophy.” New England J of Medicine, 343: 618-24, 2000.

Kim S. H., R.R. Tasker, and M.Y. Oh. “Spinal Cord Stimulation for Nonspecific Limb Pain versus Neuropathic Pain and Spontaneous versus Evoked Pain.” Neurosurgery, 48(5): 1056-1064, 2001.

Kumar, K., C. Toth, R. Nath, and P. Lang. “Epidural Spinal Cord Stimulation for Treatment of Chronic Pain-Some Predictors of Success. A 15 year experience.” Surg Neurol, 50: 110-120, 1998.

Lang, P. “The Treatment of Chronic Pain by Epidural Spinal Cord Stimulation.” AXON, 18(4): 71-73, 1997.

Ohnmeiss, D., R. Rashbaum, M. Bogdanffy. Prospective Outcome Evaluation of Spinal Cord Stimulation in Patients With Intractable Leg Pain. Spine, 21:1344-1351, 1996.

Rainov, N.G., V. Heidecke, and W. Burkert. “Short Test-Period Spinal Cord Stimulation for Failed Back Surgery Syndrome.” Minim Invasive Neurosurg, 39(2):41-44, 1996.

Segal, R., B. Stacey, T. Rudy, S. Basser, J. Markham. “Spinal Cord Stimulation Revisited.” Neurological Research, 20:391-396, 1998.

Spieglemann, R. and W.A. Friedman. “Spinal Cord Stimulation: A Contemporary Series.” Neurosurg 28:65-71, 1991.

Villavicencio, A.T., J.C. Leveque, L. Rubin, K. Bulsara, and J.P. Gorecki. “Laminectomy versus percutaneous electrode placement for spinal cord stimulation.” Neurosurgery, 46:399-406, 2000.

Contraindications

Patients contraindicated for permanent SCS therapy are those who:

- are unable to operate the SCS system
- have failed trial stimulation by failing to receive effective pain relief
- are poor surgical risks
- are pregnant

Safety Information

Warnings

Magnetic Resonance Image (MRI). Patients implanted with the Precision SCS system should not be subjected to MRI. MRI exposure may result in dislodgement of implanted components, heating of the neurostimulator, damage to the device electronics and/or voltage induction through the leads and stimulator causing an uncomfortable or "jolting" sensation.

Pediatric Use. The safety and effectiveness of spinal cord stimulation has not been established for pediatric use.

Diathermy. Shortwave, microwave and/or therapeutic ultrasound diathermy should not be used on SCS patients. The energy generated by diathermy can be transferred through the stimulator system, causing tissue damage at the lead site which may result in severe injury or death. The IPG, whether it is turned on or off, may be damaged.

Implanted Stimulation Devices. Spinal cord stimulators may interfere with the operation of implanted sensing stimulators such as pacemakers or cardioverter defibrillators. The effects of implanted stimulation devices on neurostimulators is unknown.

Implant Damage. Burns may result if the pulse generator case is ruptured or pierced and patient tissue is exposed to battery chemicals. Do not implant the device if the case is damaged.

Postural Changes. Patients should be advised that changes in posture or abrupt movements may cause decreases, or uncomfortable or painful increases in the perceived stimulation level. Patients should be advised to turn down the amplitude or turn off the IPG before making posture changes. If unpleasant sensations occur, the IPG should be turned off immediately.

Electromagnetic Interference. Strong electromagnetic fields can potentially turn the stimulator off, or cause uncomfortable or jolting stimulation. Patients should be counseled to avoid or exercise care around:

- Theft detectors or security screeners
- Power lines or power generators
- Electric steel furnaces and arc welders
- Large, magnetized stereo speakers

Precautions

Physician training is required.

Medical Devices/Therapies. The following medical therapies or procedures may turn stimulation off or may cause permanent damage to the implant, particularly if used in close proximity to the device:

- lithotripsy
- electrocautery: *Do not use monopolar cautery.*
- external defibrillation
- radiation therapy
- ultrasonic scanning
- high-output ultrasound

If any of the above is required by medical necessity, refer to “Instructions for the Physician” on page 16. Ultimately, however, the device may need to be explanted as a result of associated failure.

Automobiles and Other Equipment. Patients should not operate automobiles, other motorized vehicles, or potentially dangerous machinery/equipment with therapeutic stimulation turned on. Stimulation must be turned off first. Sudden stimulation changes, if they occur, may distract patients from attentive operation of the vehicle or equipment.

Cell Phones. While we don't anticipate any interference with cell phones, the full effects of interaction with cell phones are unknown at this time.

Post Operative. During the two weeks following surgery, it is important to use extreme care so that appropriate healing will secure the implanted components and close the surgical incisions:

Do not exercise or attempt to move heavy objects, and avoid deep bending and stretching. Temporarily, there may be some pain in the area of the implant as the incisions heal. If discomfort continues beyond two weeks, contact your physician.

If you notice excessive redness around the wound areas during this time, contact your physician to check for infection and administer proper treatment. In rare cases, adverse tissue reaction to implanted materials can occur during this period.

Implant Location. Never attempt to change the orientation or "flip" the implant. Do not "finger" or play with the implant. If the implant flips over in your body it cannot be charged. If you know that the device has turned, or if stimulation cannot be turned on after charging, contact your physician to arrange an evaluation of the system.

In some cases, the skin over your implant may become very thin over time. If this occurs, contact your physician.

Lead Location. In some instances a lead can move from its original location, and stimulation at the intended pain site can be lost. If this occurs, consult your physician who may able to restore stimulation by reprogramming the implant in the clinic or repositioning the lead during another operation.

Device Failure. Implants can fail at any time due to random component failure, loss of battery functionality, or lead breakage. If the device stops working even after complete charging (up to four hours), turn off the implant and contact your physician so that the system can be evaluated.

Storage. Do not expose the Remote Control or Charging System components to excessively hot or cold conditions. Do not leave the devices in your car or outdoors for extended periods of time. The sensitive electronics can be damaged by temperature extremes, particularly high heat. If the Remote Control or the Charging System is to be stored for a period of time, be careful that the storage temperature does not exceed -20–60 °C (-4–140 °F).

Handling. Handle the system components and accessories with care. Do not drop them or submerge them in water. Although reliability testing has been performed to ensure quality manufacturing and performance, dropping the devices on hard surfaces or in water, or other rough handling, can permanently damage the components. (See "Limited Warranty" on page 52.)

Component Disposal. Do not dispose of the Remote Control or Charger in fire. The battery in these devices can explode in fire. Dispose of used batteries in accordance with local regulations. The IPG should be explanted in the case of cremation, and returned to Advanced Bionics.

Remote Control, Charging System Cleaning. The components can be cleaned using alcohol or a mild detergent applied with a cloth or tissue. Residue from soapy detergents should be removed with a damp cloth. Do not use abrasive cleansers for cleaning.

Adverse Effects

Potential risks are involved with any surgery. In addition to those typically associated with surgery, possible risks of stimulation system implantation include:

- Lead migration, resulting in undesirable changes in stimulation and subsequent reduction in pain relief.
- System failure, which can occur at any time due to random failure(s) of the components or the battery. These events, which may include battery leakage, device fail-

ure, lead breakage, hardware malfunctions, loose connections, electrical shorts or open circuits and lead insulation breaches, can result in ineffective pain control.

- Tissue reaction to implanted materials can occur.
- Skin erosion or seroma at the IPG site can occur over time.
- Possible surgical procedural risks are: temporary pain at the implant site, infection, spinal cord compression, cerebrospinal fluid (CSF) leakage and, although rare, epidural hemorrhage, seroma, hematoma and paralysis.
- External sources of electromagnetic interference may cause the device to malfunction and affect stimulation.
- Exposure to MRI can result in heating of tissue, image artifacts, induced voltages in the neurostimulator and/or leads, lead dislodgement.
- Undesirable stimulation may occur over time due to cellular changes in tissue around the electrodes, changes in electrode position, loose electrical connections and/or lead failure.
- The patient may experience painful electrical stimulation of the chest wall as a result of stimulation of certain nerve roots several weeks after surgery.
- Over time, the implant may move from its original position.
- Weakness, clumsiness, numbness or pain below the level of implantation.
- Persistent pain at the IPG or lead site.

Instructions for the Physician

Implanted Stimulation Devices. If other implanted devices are indicated for the patient, careful screening is required to determine if safe results can be achieved before permanently implementing concurrent electrical therapies.

Postural Changes. Depending on the activity level of the patient, postural changes may affect stimulation intensity. Instruct patients to keep the Remote Control at hand at all times, and ensure that they understand how to adjust stimulation levels.

Medical Devices/Therapies. If the patient is required to undergo lithotripsy, electrocautery, external defibrillation, radiation therapy, ultrasonic scanning, or high-output ultrasound:

- Turn off stimulation at least five minutes before the procedure or application.
- All equipment, including ground plates and paddles, must be used as far away from the IPG as possible.
- Bipolar electrocautery is recommended: *Do not use monopolar electrocautery.*
- Every effort should be taken to keep fields, including current, radiation, or high-output ultrasonic beams, away from the IPG.
- Equipment should be set to the lowest energy setting clinically indicated.
- Instruct patients to confirm IPG functionality following treatment by turning on the IPG and gradually increasing stimulation to the desired level.

Package Contents

Lead Kit - Model SC-2108

(1) Lead
(1) Curved Stylet (pre-loaded in Lead)
(1) Straight Stylet
(2) Suture Sleeves
(1) Insertion Needle
(1) Lead Blank
(1) OR Cable Assembly
(2) Lead Position Labels—left and right (non-sterile)
(1) Manual
(1) Product Registration Form
(1) Temporary Patient Identification Card

Lead Extension Kit - Model SC-3108

(1) Lead Extension
(1) Skin Marker
(1) Hex Torque Wrench
(1) Tunneling Tool Assembly
(1) Manual
(1) Product Registration Form
(1) Temporary Patient Identification Card

Sterilization and Handling

Sterilization

The Advanced Bionics Lead Model SC-2108 and Lead Extension Model SC-3108 and accessories (except for the Lead Position Labels) were sterilized with ethylene oxide prior to shipment. Red lines on the green tape located near the bottom of the inner tray cover indicate exposure to the sterilization process.

Inspect the condition of the sterilization indicator and the sterile package before opening the package and using the contents. *Do not use the contents if the indicator lines are not red, if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.*

- Do not use any component that shows signs of damage.
- Do not resterilize the package or the contents. Obtain a sterile package from Advanced Bionics.
- Do not use if "Use Before" date has expired.

Note: *The lead, lead extension and accessories are intended for single use only.*

Handling

The lead is designed to perform in the hostile environment of the human body. Care must be taken to avoid damaging the lead with sharp instruments or excessive force during surgery. The following guidelines will help to ensure the longevity of components:

- Do not sharply bend or kink the lead or extension.
- Do not tie suture(s) directly to the lead or extension body; use the provided suture sleeves.
- Avoid forcing the lead into the epidural space by carefully clearing a path using the lead blank.

- Avoid pulling an implanted lead taut; provide a stress relief loop at the insertion site to minimize tension on the lead.
- Avoid handling the lead with sharp instruments; use only rubber-tipped forceps.
- Take care when using sharp instruments such as hemostats or scalpels to prevent damaging the lead.
- Wipe off any body fluids from the lead connector end before connecting it to any other component. Fluid contamination of these connections could compromise the integrity of the stimulation circuit.
- Wipe off any body fluids from the stylet before inserting or reinserting it into the lead.

Storage

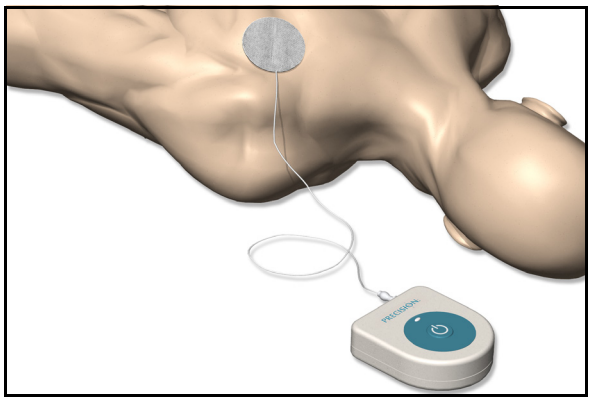
Store components between 5 °C and 40 °C (41 °F–104 °F) in an area where they are not exposed to liquids or excessive moisture. Temperatures outside of the stated range can cause damage.

Guidelines for Trial-phase Implantation

This section details the recommended procedures for trial-phase temporary implantation of the lead.

Pre-op Instructions

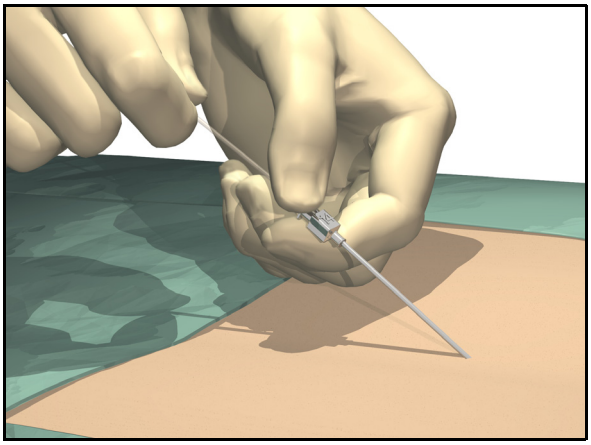
- Check that the sterile package is intact. (See “Sterilization” on page 18.)
- Ensure that a Trial Stimulator and Patient Trial Kit are available for use following lead placement. Install a new 6 volt battery (included in the Patient Trial Kit) in the Trial Stimulator.
- Be sure the Trial Stimulator and Remote Control stimulation settings have been reset. Refer to the IPG manual for links and resets.
- If monopolar testing is anticipated, place the monopolar/indifferent electrode (available separately) on the patient’s shoulder or leg and run the cable to the Trial Stimulator testing site before the patient is prepped and draped.



Lead Placement

Note: *Fluoroscopic evaluation of the lead position during this procedure will aid the physician in achieving an optimum pain coverage location, and is recommended.*

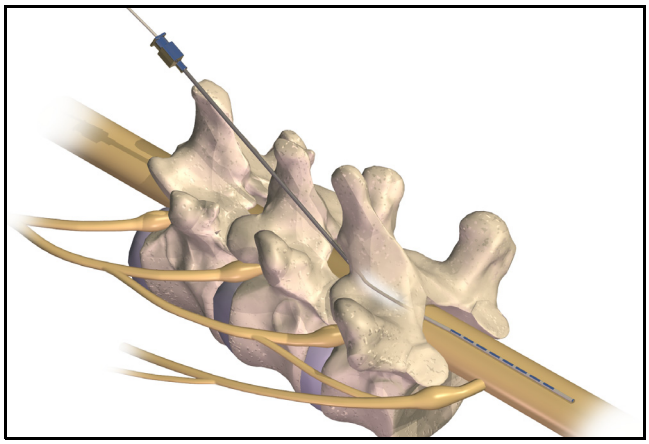
1. Position, prep and drape the patient in the usual accepted manner. Inject a local anesthetic at the needle insertion site.
2. Insert the needle into the epidural space with the opening facing up using an angle of 45° or less.



CAUTION: Use only the insertion needle provided in the Lead Kit. Other needles may damage the lead. The stamped number on the needle hub corresponds to the orientation of the bevel, which must face up. Turning the bevel ventral (down) may result in lead damage. An angle of more than 45° increases the risk of lead damage.

3. Remove the needle stylet and verify entry into the epidural space using the standard technique.

4. OPTIONAL. Under fluoroscopic guidance, insert the lead blank through the needle and into the epidural space. Advance the lead blank to the target location, then withdraw the blank.
5. Slowly insert the lead, with stylet, through the needle (lead stylet should extend completely to the tip of the lead).
6. Advance the lead to the appropriate vertebral level using fluoroscopic guidance. A sufficient length of lead (i.e., at least 10 cm, or approximately three vertebrae) should reside in the epidural space and aids in lead stabilization.



To facilitate advancement and placement, the lead body may be rotated.

Connecting the OR Cable Assembly

The OR cable extension is designed for temporary connection to the OR cable to facilitate stimulation testing outside of the sterile field. After stimulation testing, the cable extension is typically removed and the OR cable is connected directly to the Trial Stimulator for use during the trial phase.

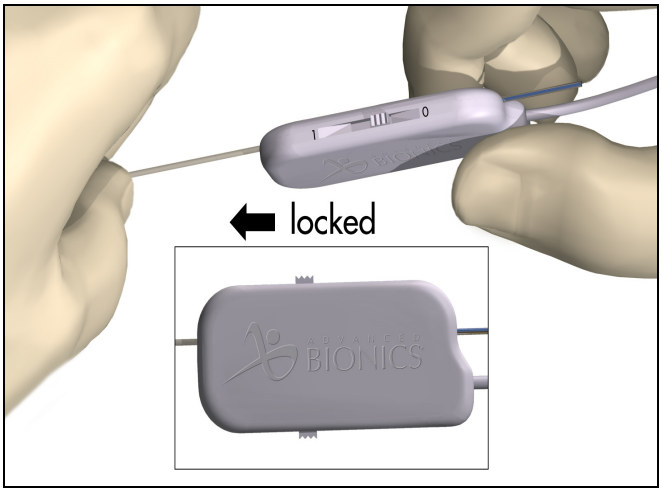
> CAUTION: Do not immerse the OR cable connector or plug in water or other liquids. The OR Cable Assembly is intended for one-time only use; do not resterilize.

1. If two leads are being implanted, wrap the non-sterile 1-L and 2-R labels around the cables at the Trial Stimulator to identify lead connections.
2. Verify that the Trial Stimulator is off.

   > CAUTION: Always turn the Trial Stimulator off before connecting or disconnecting the Cable Assemblies.

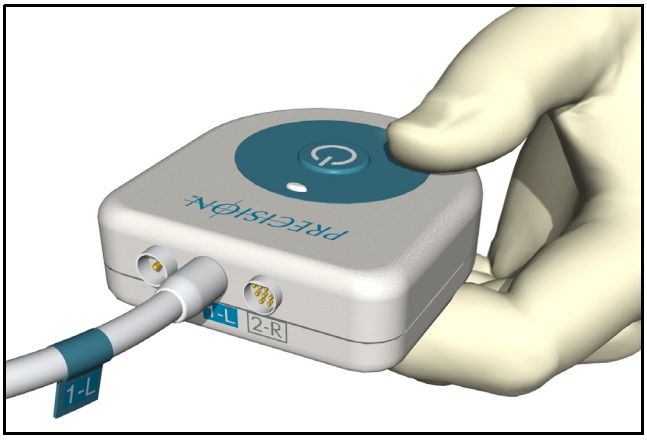
3. Check that the locking lever on the OR cable connector is in the open position (0).
4. Slide the proximal end of the lead, with stylet, into the open port on the OR cable connector.

5. Push the end of the lead into the port until it stops. Hold the lead in place while sliding the locking lever to the “1” (locked) position.



Note: *Once the lead is secured in the connector, the stylet can be manipulated in, but not removed from, the lead.*

6. Plug the OR Cable Assembly into the Trial Stimulator socket(s) labeled 1-L (left) and 2-R (right).



Superior (upper or left) leads connect to socket 1-L. Inferior (lower or right) leads connect to socket 2-R. If only a single lead is being used, connect it to 1-L.

Intraoperative Stimulation Testing

Note: *The following steps are for procedural reference only. Please refer to the BionicNavigator Software Guide for detailed stimulation testing procedures and guidelines.*

1. Test various electrode configurations to obtain paresthesia.

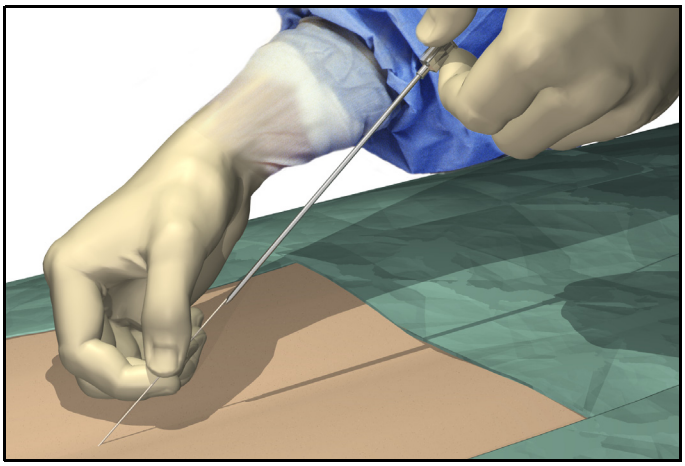
Note: *If lead repositioning is necessary, turn stimulation off before proceeding.*

2. When the desired paresthesia is achieved:
    - turn the Trial Stimulator off
    - unlock each OR cable connector and disconnect from the lead(s)
    - slowly withdraw the stylet(s)
3. Record the lead position by capturing a fluoroscopic image to be sure the leads have not moved. Retest if necessary. The image can also be used for a position comparison at closure to ensure that the leads did not move.

OPTION A: Temporary Lead Trial

1. Hold the lead distal to the needle hub to maintain lead position during needle removal.
2. Carefully withdraw the insertion needle from the epidural space by slowly pulling the needle up towards the proximal end of the lead.
3. Continue to pull the needle back approximately one centimeter at a time until the needle tip is exposed.

4. Once the needle tip is exposed, hold the lead as close to the percutaneous exit site as possible, then carefully pull the needle completely from the lead.

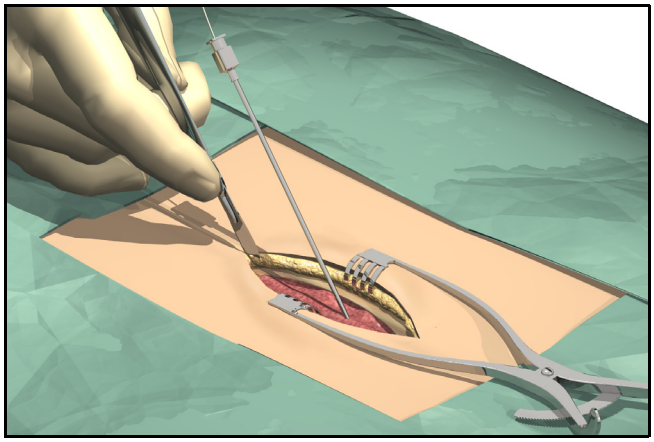


5. If desired, a small suture may be used to close the wound and stabilize the lead. Place and tape a stress relief loop and dress the wound.
6. Continue with “Connecting to the Trial Stimulator” on page 36.

OPTION B: Permanent Lead Trial

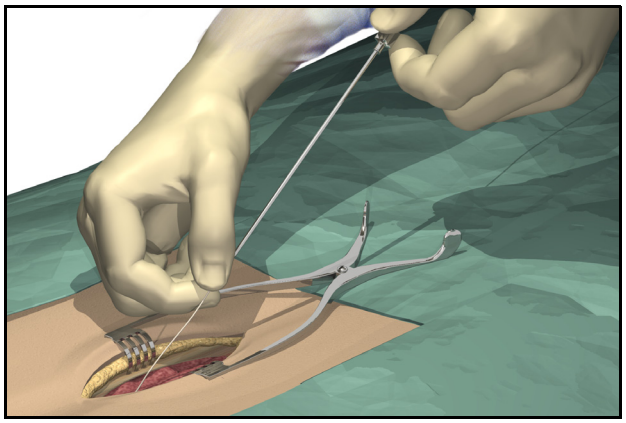
Removing the Needle

1. Cut down around the needle to access the supraspinous ligament.



2. Hold the lead distal to the needle hub to maintain lead position during needle removal.
3. Carefully withdraw the insertion needle from the epidural space by slowly pulling the needle up towards the proximal end of the lead.
4. Continue to pull the needle back approximately one centimeter at a time until the needle tip is exposed.

5. Once the needle tip is exposed, hold the lead as close to the tip as possible, then carefully pull the needle completely from the lead.

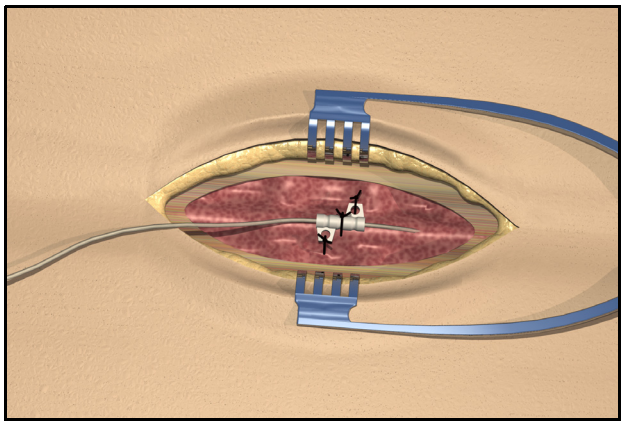


Anchoring the Lead

1. Place a suture through the supraspinous ligament or deep fascial tissue.
2. Slide a suture sleeve over the lead and down to the supraspinous ligament.
3. Ligate the sleeve onto the lead by tying a 2-0 silk or other nonabsorbable suture around the center groove of the sleeve to prevent sliding.

   CAUTION: Do not use polypropylene sutures as they may damage the suture sleeve. Do not suture directly onto the lead or use a hemostat on the lead body. This may damage the lead insulation.

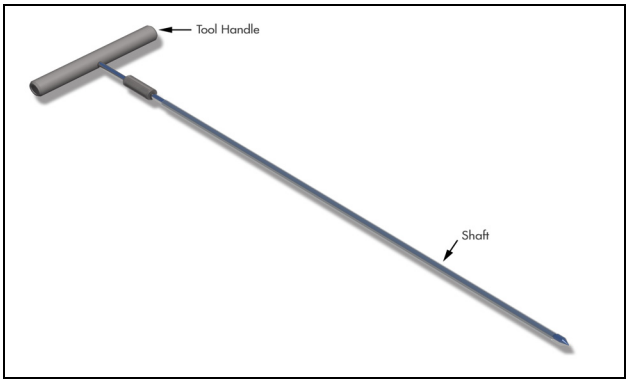
4. Suture the sleeve to the supraspinous ligament or deep fascia through the suture sleeve holes.



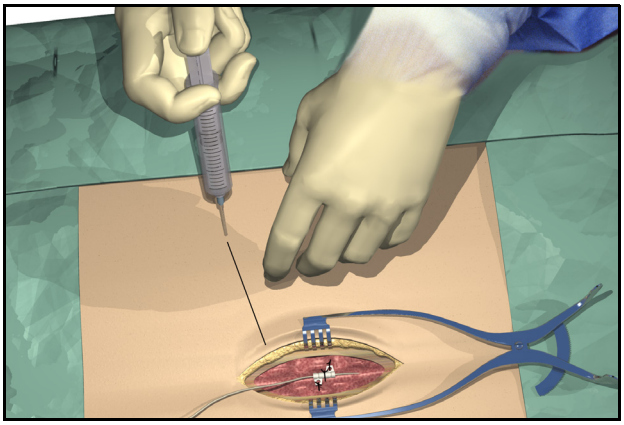
Tunneling And Connecting Extension

A tunneling tool and straw are provided with the Lead Extension Kit to facilitate percutaneous tunneling of the lead or extension.

- Attach the tunneling tool handle to the shaft by turning the locking mechanism clockwise.

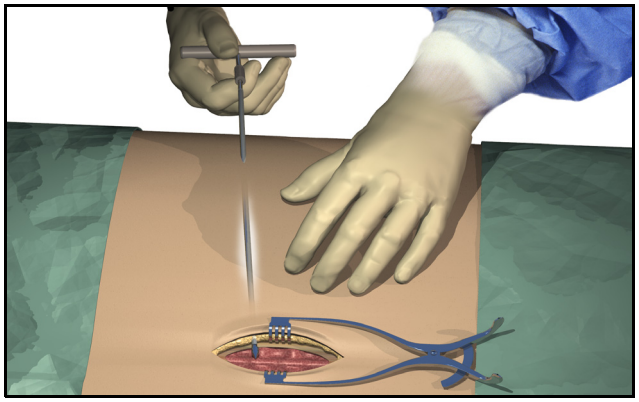


1. Mark the desired route of the tunnel.
2. Administer the appropriate local anesthetic along the tunneling path.

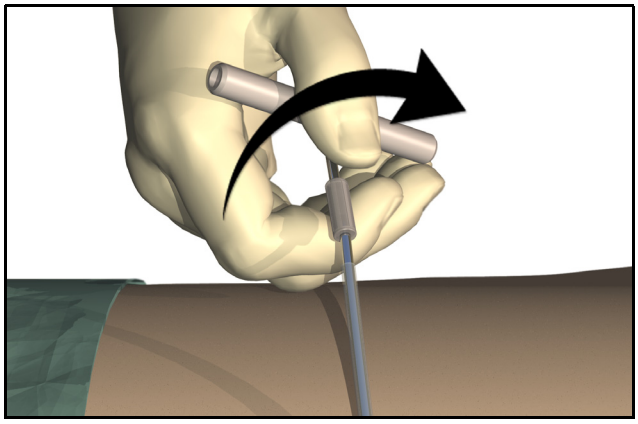


3. Make a small incision at the desired exit site.

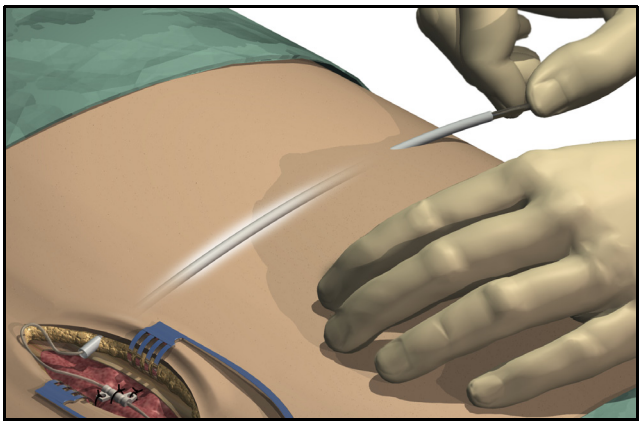
4. Create a subcutaneous tunnel from the exit site to the midline incision until the straw is visible and accessible at the exit point.



5. Unscrew and remove the tool handle.



6. Grasp the tip of the tool with one hand while holding the straw in place with the other hand. Pull the tunneling tool shaft out through the straw.
7. Push the lead or extension proximal ends through the straw, then withdraw the straw.

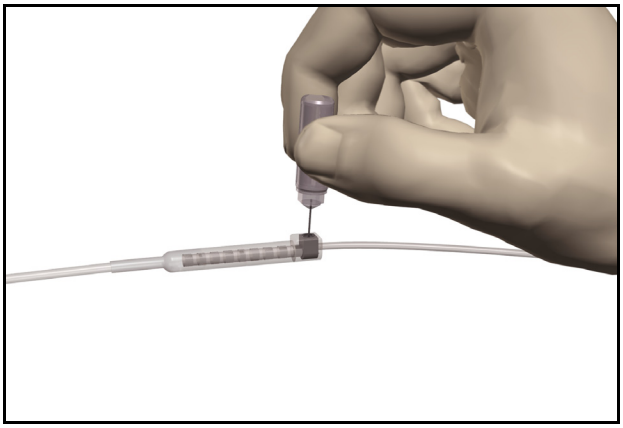


8. Wipe clean the proximal end of the lead, then insert the proximal end into the extension connector until it stops and the retention ring (long ring) is under the setscrew.

Note: • *If there appears to be an obstruction, use the torque wrench to loosen (counterclockwise) the setscrew and/or gently rotate the lead to help advance the proximal end.*

• *Ensure that the lead is fully inserted before tightening the setscrew to prevent lead damage.*

9. Using the torque wrench supplied, turn the extension connector setscrew clockwise until it clicks, indicating lock.



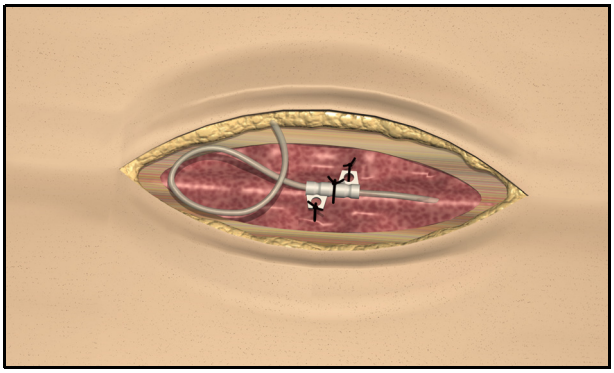
Note: • *Ensure that the wrench is fully seated in the setscrew before tightening.*

• *The wrench is torque-limited and cannot be overtightened.*

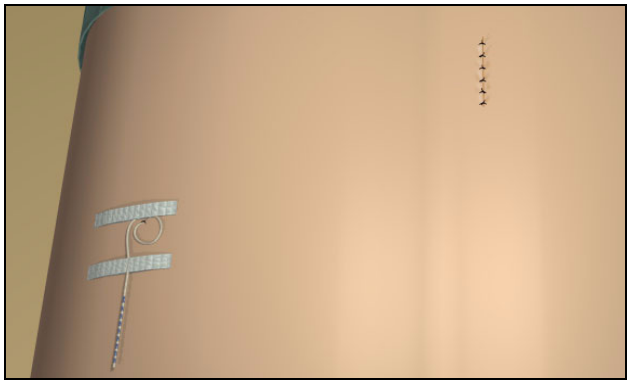
10. Form an appropriately-sized pocket using blunt dissection on either side of midline for coiled excess lead and extension connectors.

11. Place a small loop at the lead for slack. If necessary, **loosely** tie a suture around the lead-loop, but do not tighten onto the lead.

CAUTION: Tightening sutures directly on the lead can damage the lead.



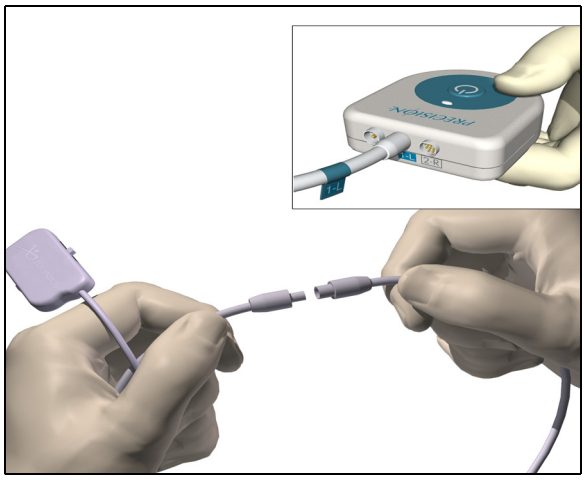
12. Carefully remove excess slack by gently pulling the extensions from the exit wound.
13. Close the midline incision.
14. If desired, a small suture may be used to close the exit wound of the extension. Place and tape a stress relief loop and dress the wound.



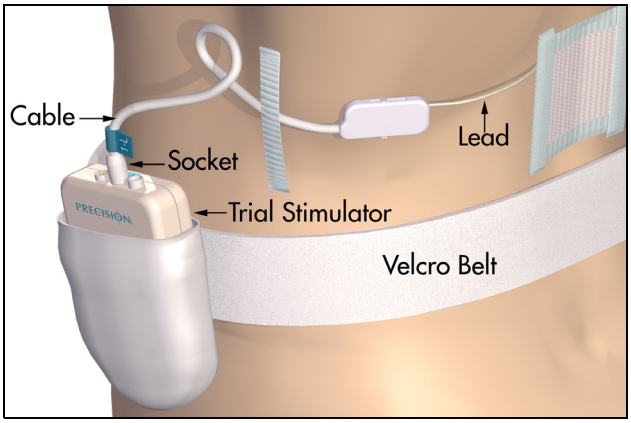
Connecting to the Trial Stimulator

1. Wipe fluids off the exposed lead connections.
2. Disconnect and discard the OR cable extension, unless extra length is needed for trial use.
3. Connect the OR cable(s) to the lead(s) or lead extensions: Slide the locking lever to “0,” fully insert the end of the extension into the port, slide the locking lever to “1.”
4. If two leads are used, connect the cable labeled 1-L to the upper or left lead, and the cable labeled 2-R to the lower or right lead. Labels are provided.
5. Next, connect the right and left-sided OR cables to the Trial Stimulator, referencing the position labels previously fixed to the cables.

   If only one lead is used, connect the OR cable to 1-L on the Trial Stimulator.



6. Fit the Velcro® belt to the patient, cut off the excess length, and place the Trial Stimulator in the belt pocket.



Guidelines for Permanent Implantation

This section details the procedures for

- tunneling the lead/extension as part of an IPG implant
- connection of lead/extension to the IPG

The Tunneling Tool Assembly used in this procedure is provided with the Precision device as part of the IPG Kit.

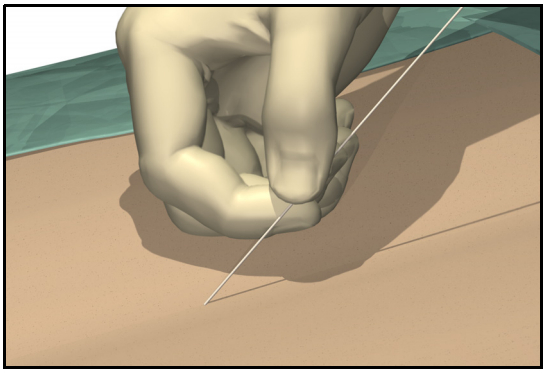
Percutaneous Lead/Extension Removal

Before revising a trial system for chronic stimulation, the exposed portion of the lead or extension must be removed. The method chosen from the choices below will depend upon how the patient was prepared for the trial phase.

Remove bandages and properly cleanse the exit site.

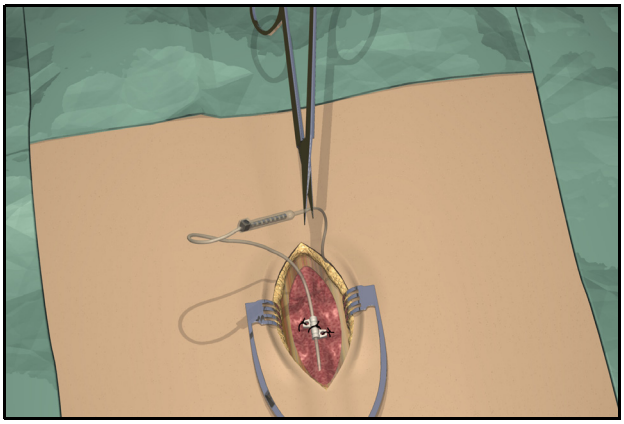
Option A. Temporary Lead Removal

1. Clip sutures if used to secure the trial lead(s) in place.
2. Remove the lead(s) completely and discard.



Option B. Extension Removal

1. Open the midline incision to expose the lead and connector.
2. Cut the lead extension at the connector.

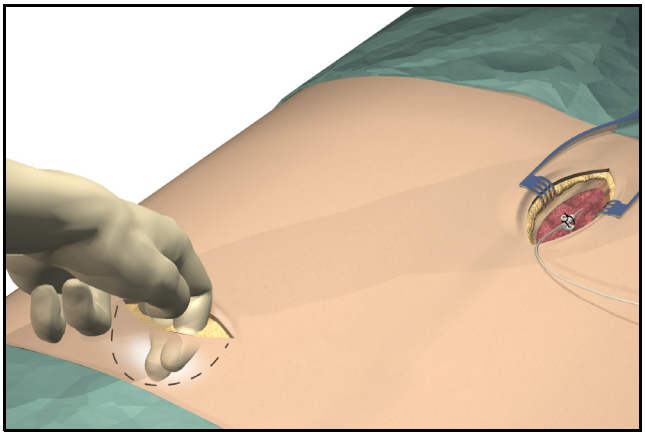


3. Pull the lead extension through the tunnel and away from body at the externalized site.
4. Loosen the connector setscrew using the torque wrench provided. Disconnect and remove the connector.

Note: *Connect a new lead extension, if necessary, to reach the selected IPG site.*

IPG Implantation

1. Ensure that the area surrounding the lead entry site is incised to a dimension that will accommodate the tunneling tool. Check that the lead is securely sutured with the suture sleeve.
2. Select and mark the intended IPG site several inches away from the previously externalized leads, and create an incision at the top of the site.
3. Create a subcutaneous pocket no larger than the IPG outline at a depth of up to 3/4 inch (2.0 cm) from the surface.



Note: • *Using the template will help guide the correct pocket sizing. It is important to keep the pocket small to reduce the chances of patient manipulation and IPG flipping.*

• *Implant charging could become ineffective at depths greater than 3/4 inch (2.0 cm).*

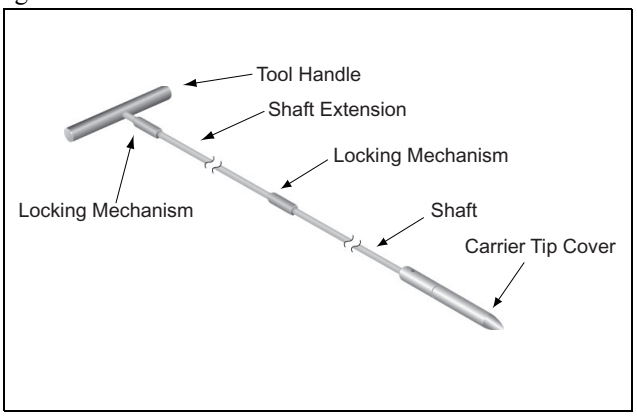
Tool Assembly

The tunneling tool provided with the IPG includes a shaft extender to be used for up to two leads (with or without extensions).

1. Attach the handle to the tunneling tool shaft by turning the locking mechanism clockwise.

Note: *For more length, attach the shaft extension to the handle, and then attach the carrier shaft.*

2. Thread the tip cover onto the tunneling tool and tighten by turning clockwise.



Tunneling The Lead

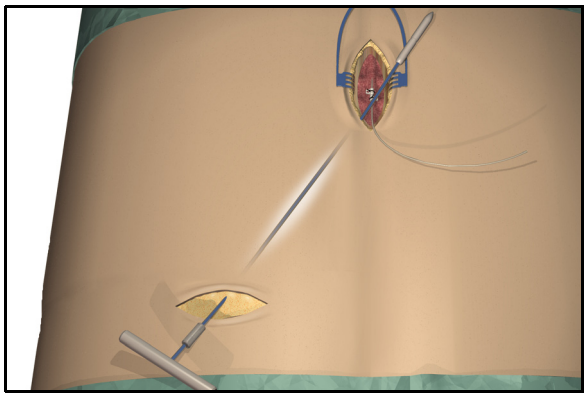
1. Mark the desired route of the tunnel.
2. Administer the appropriate local anesthetic along the tunneling path.

Note: *Check that the tunneling tool tip is securely threaded onto the carrier.*

3. OPTIONAL. If necessary, bend the tool shaft to conform to the patient's body.

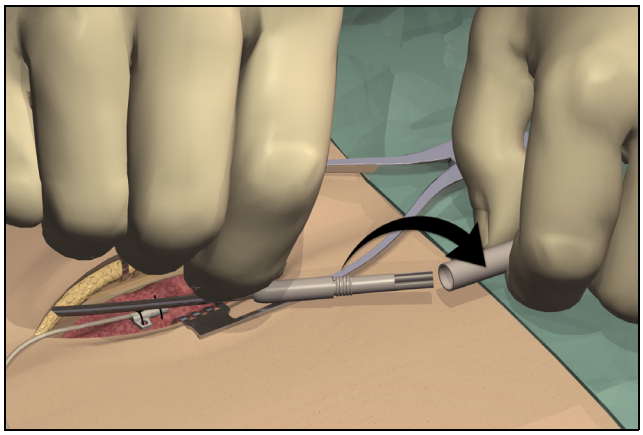
   CAUTION: Do not bend locking joints.

4. Create a subcutaneous tunnel from the IPG site to the midline incision.



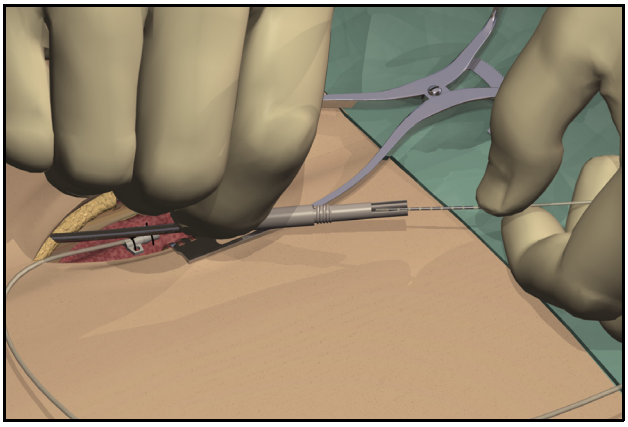
Note: *Deep tunneling is not recommended.*

5. Once the tunneling tip is completely exposed at midline, press it toward the shaft and turn it counterclockwise to remove it for access to the carrier.



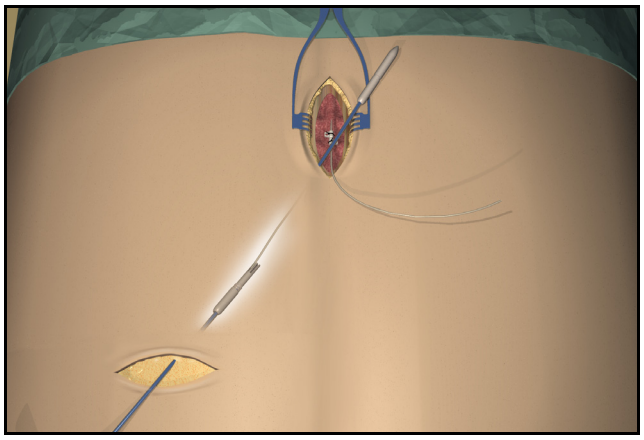
Note: *You may feel the tip slide back before the cover begins to unscrew.*

6. Carefully position each lead or extension into the carrier shaft and press the lead/extension into the groove.



Note: *If necessary, swivel the carrier by pulling it away from the handle and turning it to get better access to the cavities.*

7. Gently pull the tunneling tool back through the tunnel.



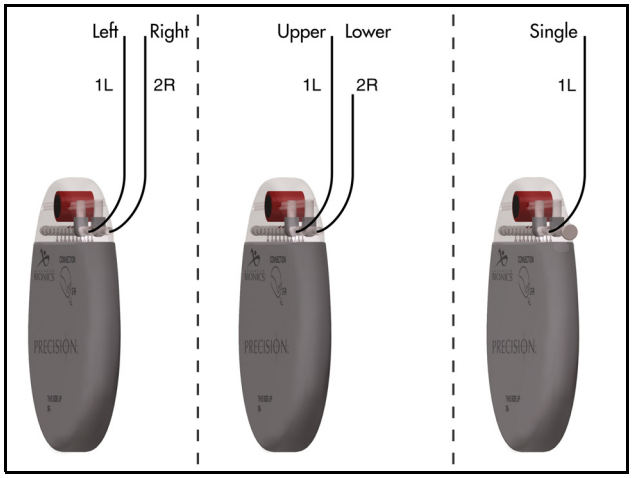
8. Gently lift the lead(s) out of the locking groove(s).
9. Wipe off any fluids from the proximal end of the lead(s).

Connecting To the IPG

Before implanting the IPG, refer to the IPG Implant Manual**.**

Dual Lead Connection

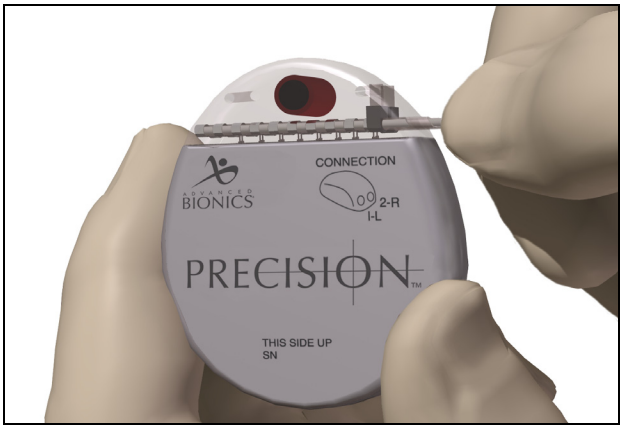
- Superior (upper or left) leads connect to IPG port 1-L.
- Inferior (lower or right) leads connect to IPG port 2-R.



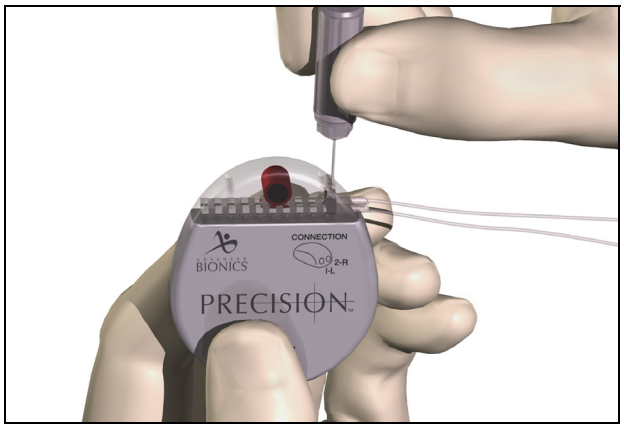
Single Lead Connection

- Connect a single lead to IPG port 1-L.
- Plug port 2-R with the connector plug supplied in the IPG Kit.

1. Fully insert the lead(s) into the IPG port(s). When the lead is properly inserted, the lead will stop and the retention ring will be located under the setscrew.



2. Pass the torque wrench through the slit in the septum located on the top of the IPG header and tighten both set screws, one at a time, until the torque wrench “clicks,” indicating lock.



Note: • *Ensure that the lead is fully inserted before tightening the setscrew to prevent lead damage.*

- *If the connector plug is used in port 2-R, it is still necessary to tighten the setscrew as described.*
- *The wrench is torque-limited and cannot be overtightened.*

3. Place the IPG in the subcutaneous pocket with “This Side Up” facing towards the skin.
4. Coil excess lead or extension under the IPG.

Note: *To confirm good connections, check impedances before tightening the setscrew.*

5. Secure the IPG in the pocket by suturing through the holes in the connector.
6. Close and dress the wound(s).

Specifications and Technical Data

Lead

Part	Specifications
Model Number	SC-2108
Lead Lengths	30, 50, 70 cm
Lead Shape	In-line
Lead Diameter	1.3 mm
Number of Electrode Contacts	8
Electrode Length	3 mm
Electrode Spacing	1 mm
Contact Material	Platinum/Iridium
Insulation Material	Polyurethane
Conductor Material	Shell: MP35N Core: MP-DFT (28% Ag)
Conductor Resistance	< 7 Ohms

Lead Extension

Part	Specifications
Model Number	SC-3108
Extension Lengths	15, 25, 35 cm
Extension Diameter	1.3 mm
Number of Electrode Contacts	8
Contact Material	Platinum/Iridium, MP35N, Stainless Steel
Insulation Material	Polyurethane, Silicone
Conductor Material	MP35N
Conductor Resistance	< 10 Ohms

Registration Information

In accordance with international practice and regulatory legislation in some countries, a registration form is packed with each Advanced Bionics Corporation lead/lead extension.

The purpose of this form is to maintain traceability of all products and to secure warranty rights. It also allows the institution involved in the evaluation or replacement of a specific implanted lead, accessory or device to gain quick access to pertinent data from the manufacturer.

Fill out the registration form included in the package contents. Return one copy to Advanced Bionics, keep one copy for patient records, and provide one copy to the patient and physician.

Advanced Bionics Corporation
25129 Rye Canyon Loop
Valencia, California 91355
Attention: Customer Service Department

Technical Service

Advanced Bionics Corporation has highly trained service professionals located worldwide to assist you. The Technical Service Department is available to provide technical consultation 24 hours a day.

In North America please call (866) 566-8913 to speak to a representative.

Limited Warranty

Advanced Bionics® Corporation warrants to the patient that the Linear Lead, Model SC-2108, and Extension, Model SC-3108, are free from defects in workmanship and materials for a period of one (1) year from the date of implantation.

A Lead or Extension that fails to function within normal tolerances within (1) year from the date of surgery is covered under this Limited Warranty. The liability of Advanced Bionics® under this warranty shall be limited to: (a) replacement with a functionally equivalent Lead or Extension; or (b) full credit equal to the original purchase price to be applied towards the purchase of a new Lead or Extension. Product claims under Advanced Bionics® Limited Warranty are subject to the following conditions and limitations:

1. The product registration card must be completed and returned to Advanced Bionics® within 30 days of surgery in order to obtain warranty rights.
2. The Lead or Extension must be returned to Advanced Bionics® (or authorized agent) within 30 days of malfunction or discovery of defect, and shall be the property of Advanced Bionics®.
3. The Lead or Extension must be implanted prior to the “use before” date.
4. Failure of the Lead or Extension must be confirmed by Advanced Bionics®. This warranty specifically excludes defects or malfunctions caused by: (a) fire, floods, lightning, natural disasters, water damage and other calamities commonly defined as “Acts of God”; (b) accident, misuse, abuse, negligence, or the customer’s failure to operate the Lead or Extension in accordance with manufacturer's instructions; (c) unauthorized attempts to repair, maintain, or modify the equipment by the customer or any unauthorized third party; or (d) attachment of any equipment not supplied by Advanced Bionics® without prior approval.

a. This warranty does not include surgical accessories used with the Linear Lead or Extension.

5. The decision as to product replacement or credit shall be made solely at the discretion of Advanced Bionics®. For a replacement Lead or Extension, the warranty will run only to the end of the warranty period for the original Lead or Extension that was replaced.

This warranty is in lieu of any other warranty, expressed or implied, including any warranty of merchantability or fitness for intended use. Except as expressly provided by this Limited Warranty, Advanced Bionics® shall not be responsible or liable for any direct, consequential or incidental damages caused by device malfunction, failure or defect, whether the claim is based on warranty, contract, tort or otherwise.

The following is federal government communications regulation information about the Precision™ System.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received including interference that may cause undesired operation.

The Precision™ System components should only be serviced by Advanced Bionics. Do not attempt to open or repair any of the components. Unauthorized opening of or attempts to repair the components will void the warranty.

Changes of modifications to this product not authorized by Advanced Bionics Corporation could void the FCC Certification and negate your authority to operate this product.